Background Information: Human Health Criteria and Fish Consumption Rates

Purpose: Provide AA with background information regarding EPA's methodology for deriving national recommended human health criteria, science-based fish consumption rates (FCRs), and EPA's policy and legal bases for ensuring protection of high fish consumers, including tribes with treaty protected rights.

304(a) Ambient Water Quality Criteria Recommendations for Human Health:

- Under CWA section 304(a), EPA is required to periodically develop and publish ambient water quality criteria (AWQC) (*i.e.,* 304(a) criteria) that reflect the latest scientific knowledge on the effects of pollutants on human health and the biological community.
- These criteria are recommendations, not rules; they do not automatically become part of a State or authorized Tribe's water quality standards. States and authorized Tribes may adopt the 304(a) recommended criteria that EPA publishes, modify EPA's criteria to reflect site-specific conditions, or adopt different criteria based on other scientifically-defensible methods.
- In its 2015 update[1], EPA revised 94 of the existing 304(a) recommended HHC to reflect the latest scientific information, including updated exposure factors (body weight, drinking water intake rate, fish consumption rate), bioaccumulation factors, and toxicity factors (reference dose, cancer slope factor). This update followed the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000).[2]
    - EPA accepted written comments from the public on the draft updated HHC from May to August 2014 and provided responses to those comments upon finalization of the HHC.

EPA's 2000 Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health:

- To protect people from cancer and non-cancer effects from pollutants in drinking water and fish and shellfish, states establish human health criteria (HHC) for carcinogens and non-carcinogens for their waters that are designated for such uses (e.g., protection and propagation of fish, shellfish, and wildlife; recreation in and on the water).
    - HHC represent concentrations of chemicals or conditions in a water body that are not expected to cause chronic adverse effects to human health.
- Beginning in 1992, EPA worked for eight years to develop its 2000 *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. The 2000 Human Health Methodology underwent review by EPA's Science Advisory Board, multiple stakeholder reviews, a four-month public comment period with public meeting, and two White House reviews.
- EPA follows its 2000 Human Health Methodology when developing new or revised 304(a) recommended HHC, and when promulgating water quality standards (WQS) for a State or authorized Tribe under Section 303(c) of the CWA.
- States and authorized Tribes commonly use EPA's 2000 Human Health Methodology when deriving their own HHC. Although the 2000 Human Health Methodology defines the default approaches and values that EPA uses in developing national recommended HHC, it strongly encourages States and

[1] [HYPERLINK "https://www.epa.gov/wqs-tech/final-rulemaking-update-national-water-quality-standards-regulation"]
[2] [HYPERLINK "https://nepis.epa.gov/Exe/ZyPDF.cgi/20003D2R.PDF?Dockey=20003D2R.PDF"]

authorized Tribes to consider local data and information (e.g., on bioaccumulation and exposure factors), and provides scientifically valid methods on how to do so.

Human Health Criteria Equation

$$\text{AWQC (Ambient Water Quality Criteria)} = \frac{\text{toxicity value x body weight}}{\text{drinking water intake rate} + (\textbf{FCR} \times \text{bioaccumulation factor})}$$

- FCR is the **fish consumption rate**, which indicates the amount of fish and shellfish consumed by a person each day.

  Toxicity value (non-carcinogens and threshold carcinogens) = (RfD × RSC)
  Toxicity value or risk specific dose (carcinogens) = (CRL / CSF)

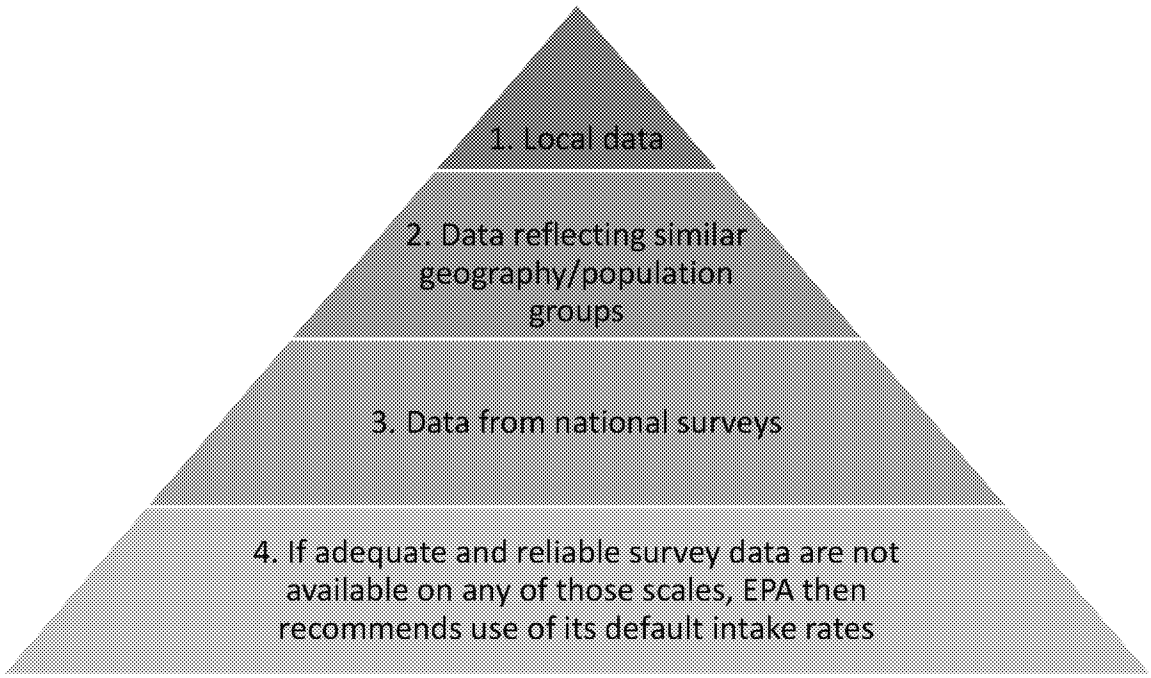
- RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime.
- RSC is the relative source contribution, or the percentage of total exposure expected to come from AWQC-rated sources (drinking water and inland/nearshore fish/shellfish). The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. Exposures outside the RSC include, but are not limited to, exposure to a particular pollutant from marine fish and shellfish consumption (which is not included in the national default FCR), non-fish food consumption (e.g., fruits, vegetables, grains, meats, poultry), dermal exposure, and respiratory exposure.
- CRL is the excess incremental lifetime cancer risk posed by the presence of a substance in water (e.g., one in one hundred thousand (10^{-5}) or one in one million (10^{-6})). States and authorized Tribes choose between these rates, and EPA recommends that the risk to more highly exposed groups does not exceed the one in ten thousand (10^{-4}) level. EPA also notes in its 2000 Human Health Methodology that states can choose a more stringent risk level (e.g., 10^{-7}), and that EPA will use the 10^{-6} risk level when developing 304(a) criteria or promulgating criteria for States and authorized Tribes under Section 303(c).
- CSF is the cancer slope factor, or the upper bound estimate (approximating a 95% confidence limit) of the increased cancer risk from a lifetime of oral exposure to a stressor.

- The 2000 Human Health Methodology recommends using a combination of median, mean, and upper percentile values as inputs for deriving HHC to achieve the goal of protecting the majority of the target population from chronic adverse health effects.
  - EPA uses the median bioaccumulation value, the mean body weight, and the **90th percentile FCR** and drinking water intake rate.
- EPA's recommendation is for HHC to provide a high level of protection for the target population, while recognizing that more highly exposed "subpopulations" may face greater levels of risk.

- EPA's 2000 Human Health Methodology recommends that States assess whether there might be more highly exposed populations that require the use of a higher FCR to protect them as the "target population group(s)."
- The 2000 Human Health Methodology does not speak to or expressly envision the unique situation of setting HHC for waters where there is a tribal subsistence fishing designated use.

Fish Consumption Rate:

- CWA Section 101(a)(2) states that "it is the national goal that wherever attainable, an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water be achieved by July 1, 1983."
- CWA Section 303(c)(2)(A) states that "Such [water quality] standards shall be such as to protect the public health or welfare. . . taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes…"
- EPA interprets the uses under Section 101(a) of the CWA to include, at a minimum, **designated uses providing for the protection of aquatic communities and human health related to consumption of fish and shellfish**. In other words, not only can fish and shellfish thrive in a waterbody, but when caught, can also be safely eaten by humans. This interpretation satisfies the CWA Section 303(c)(2)(A) requirement that WQS protect public health.
- As described in EPA's 2000 Human Health Methodology, the level of fish consumption varies by geographical location. EPA recommends that States and authorized Tribes consider developing HHC to protect highly exposed population groups and **use local or regional data in place of a default value as more representative of their target population(s).**
- EPA suggests a four-preference hierarchy for States and authorized Tribes that encourages use of the best local, state, or regional data available to derive fish consumption rates:



- The **national default FCR of 22 grams per day for the general population** includes inland and nearshore fish and shellfish from local, commercial, aquaculture, interstate, and international sources.
    - This ensures that consumers can safely consume from local waters the amount of fish they would normally consume from all inland and nearshore waters.
    - This rate represents the 90th percentile consumption rate *(policy decision)* of inland and nearshore finfish and shellfish (raw weight, edible portion) for the U.S. adult population 21 years of age and older, **based on National Health and Nutrition Examination Survey (NHANES) data** *(science decision)* from 2003 to 2010 (as reported in Table 9, USEPA 2014).[3]
    - The analysis supporting EPA's national default rate underwent external peer review and was published in a 2014 EPA technical report. EPA incorporated this rate in its 2015 304(a) recommended HHC updates.
- When deriving its national 304(a) recommendations, EPA does not include marine fish and shellfish in the FCR, and instead addresses that exposure route using the relative source contribution (RSC). However, EPA recognizes that accounting for marine species in the FCR may be more appropriate for protecting the population of concern. If a State or authorized Tribe chooses to include marine fish in their selected FCR, EPA recommends adjusting the RSC accordingly.
    - For example, Oregon, Washington, and Idaho all included certain marine species (i.e., salmon) in their selected FCRs. Continuing research in the Pacific Northwest supports including salmon because they are likely accumulating certain contaminants from nearshore waters, and may acquire contaminants directly from inland waters when returning to spawn.
- The **national default FCR for subsistence fishers is 142.4 grams per day**. This is based on the 99th percentile consumption rate of fish and shellfish from inland and nearshore waters for the U.S. adult population and was derived from 1994-1996 USDA Continuing Survey of Food Intakes by Individuals (CSFII) data. EPA published this recommended rate in its 2000 Human Health Methodology, but did not have sufficient data to update the subsistence default rate in 2014 when EPA updated the general population rate.
    - This default rate for subsistence fishers is corroborated by data for high consuming groups in specific locations, for example Native Americans in the Pacific Northwest where upper percentile current FCRs range from 100 to 800 grams per day.

Application of Treaty Rights to Inform Selection of a FCR:

- For decades, Indian tribes with fishing rights reserved in federal law have asserted their rights in the context of state and federal actions, and have won protections for those rights in federal courts.
- EPA generally has broad discretionary authority under the CWA in determining whether State WQS comply with the CWA. In exercising its discretion, however, EPA must ensure that its decisions comply with other applicable laws, including federal treaties and statutes that reserve fishing and other resource rights to a Tribe. CWA section 511 specifically provides that the Act "shall not be construed as . . . affecting or impairing the provisions of any treaty of the United States."

[3] EPA's previously recommended rate of 17.5 grams per day (noted in the 2000 Human Health Methodology) was based on the 90th percentile consumption rate of fish and shellfish from inland and nearshore waters for the U.S. adult population and was derived from 1994-1996 USDA Continuing Survey of Food Intakes by Individuals (CSFII) data.

- In the limited areas in which tribal fishing rights apply, since 2014, EPA has harmonized such rights with CWA WQS requirements by ensuring that the FCR and CRL inputs to HHC represent and protect a sustenance level of fish consumption.
- To ensure that HHC protect a sustenance level of consumption, EPA concluded that the Tribal population exercising their reserved fishing rights must be treated as the "target general population" (rather than a high-consuming sub-population, which would allow for a lower level of protection).
- EPA's approach is consistent with views of the Department of the Interior Office of the Solicitor, who issued a February 2015 letter to EPA concluding that "fundamental, longstanding tenets of federal Indian law support the interpretation of tribal fishing rights to include the right to sufficient water quality to effectuate the fishing right."

Case-specific Examples (Washington, Idaho, Maine):

Washington

- In November 2016, EPA approved and disapproved certain HHC submitted by WA. WA's selected FCR and CRL were protective of tribal subsistence fish consumers; EPA disapproved where WA's HHC were not based on sound science to protect the designated use. EPA promulgated federal HHC in place of the disapproved state HHC.
    - WA's use of bioconcentration factors (BCFs) instead of bioaccumulation factors (BAFs) was the driver for 90% of the disapprovals; WA's use of a relative source contribution (RSC) of 1 instead of an RSC less than 0.8 was the driver for 10% of the disapprovals.
- In February 2017, several industry groups submitted a petition requesting that EPA reconsider its action on the state HHC and repeal the federal HHC rule. Tribes and environmental groups sent letters in 2017 asking EPA to deny the industry petition.
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Idaho

- EPA is reviewing ID's HHC, which were submitted on December 13, 2016. ID's HHC are based on current science but use a lower FCR and CRL than EPA used in its federal promulgations in ME and WA.
- The CWA deadlines to either approve or disapprove ID's criteria have passed.
- EPA is under a settlement agreement with the Idaho Conservation League (ICL) to either approve ID's HHC or sign a notice of proposed federal rulemaking for ID by June 13, 2017. ICL stated its intent not to press EPA to comply with the agreement "for the foreseeable future."
- EPA previously expressed concern that ID's HHC are not protective of tribal members exercising treaty-reserved fishing rights and do not ensure protection of downstream waters in WA and OR. However, EPA is exploring options that include concluding that ID satisfied applicable treaty right obligations.
- EPA is engaged in government-to-government consultation with the ID tribes on EPA's review. The tribes have asked that EPA continue to offer consultation and coordination meetings prior to any final EPA decision.

Maine

- ME has challenged EPA's 2015 approvals of a sustenance fishing designated use for tribal waters (including EPA's interpretation of ME's "fishing" use in tribal waters to include sustenance fishing) and EPA's 2015 disapprovals of the state's HHC because the HHC did not protect that sustenance fishing use.
- EPA committed to defend the challenged actions. Maine filed its opening brief on February 16, and EPA's opening brief is due on June 21, 2018.
- Two of the four affected tribes are intervenors.
- Tribal waters are a small fraction of waters in the state, and there is only one potentially affected discharger.
- Following the 2015 disapprovals, in 2016 EPA promulgated HHC for tribal waters (ME did not challenge the rule). ME is asking EPA to approve the state's 2006 HHC, which no longer meet the sound science regulatory requirement.

Appendix A. Summary Sheet for Actions in Maine, Washington, and Idaho

	Maine	Washington	Idaho
Scope of Tribal Reserved Rights	Indian Country (IC)	Statewide	Statewide (however, discussions with the tribes re: scope are on-going)
Relevant Actions Taken To-Date	1) Approved 'sustenance fishing' as a designated use for waters in IC 2) Disapproved for IC ME's HHC (from 2006) that did not protect the sustenance fishing use[4] 3) Issued a CWA 303(c)(4)(B) Administrator's Determination that new/revised HHC were necessary to protect the sustenance fishing use in IC 4) Promulgated a federal rule applicable to IC for the HHC that EPA disapproved (effective 1/18/17)	1) Interpreted WA's statewide 'fish harvesting' designated use to include 'subsistence fishing' 2) Issued a CWA 303(c)(4)(B) Administrator's Determination that new/revised HHC were necessary to protect the statewide subsistence fishing use 3) Approved WA's HHC (from 2016) where they were stringent enough to protect the subsistence fishing use (approx. ¼ of the HHC) 4) Disapproved WA's HHC where they were not stringent enough to protect the subsistence fishing use (approx. ¾ of the HHC) 5) Promulgated a federal rule applicable statewide for the HHC that EPA disapproved (effective 12/28/16)	1) Submitted numerous public comment letters to ID, last in January 2017, explaining EPA's: a. Interpretation of ID's statewide 'fishing' designated use to include 'subsistence fishing' b. Concern that ID's HHC (from 2016) are not sufficiently protective of a subsistence use with tribes as the target population, because the HHC are based on the *mean* of the Nez Perce tribe's current fish consumption rate (FCR) of 66.5 g/day and a cancer risk level (CRL) of 10^{-5} c. Concern that ID's HHC will not protect waters in downstream states

[4] There are also other EPA disapprovals **not based on tribal issues** but still covered by the petitions asking EPA to reconsider its actions in Maine. EPA's rule addressed most (but not all) of these disapprovals, including:

- Six WQS for waters in Indian lands - recreational and shellfishing bacteria criteria to protect human health; clarification that natural conditions provisions cannot be applied to HHC; mixing zone policy; aquatic life criteria for ammonia, pH, and tidal temperature). EPA disapproved these WQS because they were not protective of applicable designated uses.
- EPA also disapproved two WQS state-wide – dissolved oxygen in Class A waters and a provision waiving WQS in event of an oil spill - and one WQS only for Maine waters outside of Indian lands (phenol criteria to protect human health) because they were not protective of applicable designated uses.

Pending Actions and Deadlines	• File EPA's Opening Brief in Litigation on Actions 1 and 2 Above ○ **Deadline: 6/21** • Respond to Petition to Reverse All Actions Above ○ **Deadline: None**[5]	• Respond to Petition to Reverse All Actions Above ○ **Deadline: None**[5]	• Act on ID's HHC Submittal ○ **Deadline: None**[6]
Key Differences Between State and EPA Positions	**Deliberative Process / Ex. 5**		

[5] Section 555(e) of the Administrative Procedure Act states, "**Prompt notice** shall be given of the denial in whole or in part of a written application, **petition**, or other request of an interested person made in connection with any agency proceeding" (emphasis added).

[6] EPA is under settlement agreement with the Idaho Conservation League (ICL) to either approve Idaho's HHC (submitted on December 13, 2016), or sign a notice of proposed federal rulemaking for Idaho within six months of Idaho's submission, by June 13, 2017. ICL stated its intent not to "enforce the related aspects of our agreement and/or seek any remedies outlined in the agreement for the foreseeable future" in order to give EPA sufficient time to evaluate the state submittal. In addition to the settlement agreement, under the CWA, EPA has a mandatory duty to either approve a state's WQS within 60 days from the date of submission (Feb 13, 2017, in this instance), or disapprove within 90 days from the date of submission (March 13, 2017, in this instance).

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